



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Ave, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX (3 of 3)

Date July 5, 2019	EPA Reg. No./File Symbol 63838-EI	Page 1 of 5
Applicant's/Registrant's Name & Address: Enviro Tech Chemical Services, Inc., 500 Winmoore Way, Modesto, CA 95358	Product ReducX	

Ingredient(s): **Octanoic Acid – Generic Matrix for Technical Active**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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TOXICOLOGY

870.3100	Subchronic Rodent Oral Toxicity, 90-Day	43843507	Mycogen (Company No. 53219)	OLD	Footnote 1
870.3250	Subchronic Dermal Toxicity - 90 Day	Agency Document	Submitter Not Indicated	PL	Footnote 2
870.3465	90-day Inhalation	CITE-ALL	----	----	----
870.4100	Chronic Feeding - (rodent)	43961801	Mycogen (Company No. 53219)	OLD	Footnote 3
870.4100	Chronic Feeding - (nonrodent)	43961801	Mycogen (Company No. 53219)	OLD	Footnote 3
870.4200	Oncogenicity-Rat	43961801	Mycogen (Company No. 53219)	OLD	Footnote 3
870.4200	Oncogenicity-Mice	43961801	Mycogen (Company No. 53219)	OLD	Footnote 3
870.3700	Teratology-Rat	43843508	Mycogen (Company No. 53219)	OLD	Footnote 3
870.3700	Teratology--Rabbit	Waiver	----	----	Footnote 4
870.3800	2-Generation Reproduction	Waiver	----	----	Footnote 4
870.5100	Genetic Toxicity-Ames	43603703	Mycogen (Company No. 53219)	OLD	Footnote 5
870.5300	<i>In vitro</i> Mammalian Cell Gene Mutation Test	42937901	Mycogen (Company No. 53219)	OLD	Footnote 5
870.5375	<i>In vitro</i> Chromosome Aberration Assay	40943006	Mycogen (Company No. 53219)	OLD	Footnote 5
870.5395	Mammalian Erythrocyte Micronucleus Test	43603702	Mycogen (Company No. 53219)	OLD	Footnote 5
870.5500	Unscheduled DNA Synthesis	40943007	Mycogen (Company No. 53219)	OLD	Footnote 5
870.7485	Metabolism and Pharmacokinetics	Waiver	----	---	Footnote 4

ECOLOGICAL EFFECTS

850.2100	Avian Oral LD50 (bobwhite)	Waiver	----	---	Footnote 6
850.2200	Avian Dietary LC50 (bobwhite)	Waiver	----	----	Footnote 6
850.2200	Avian Dietary LC50 (mallard)	Waiver	----	----	Footnote 6
850.1075	Freshwater Fish LC50 (bluegill sunfish)	Waiver	----	----	Footnote 6
850.1075	Freshwater Fish LC50 (rainbow trout)	Waiver	----	----	Footnote 6
850.1010	Freshwater Invertebrates LC50 (Daphnia)	Waiver	----	----	Footnote 6

Signature <i>Mike Harvey</i>	Name and Title: Michael Harvey, CEO	Date 7-5-2019
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Applicant's/Registrant's Name & Address: Enviro Tech Chemical Services, Inc., 500 Winmoore Way, Modesto, CA 95358	Product ReducX	

Ingredient(s): **Octanoic Acid – Generic Matrix for Technical Active**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1025-850.1055	Acute Toxicity to Estuarine/Marine Organisms (Sheepshead minnow, mysid shrimp and eastern oyster)	Waiver	-----	----	Footnote 6
850.1300	Daphnid Chronic Toxicity	Waiver	-----	----	Footnote 6
850.1300	Daphnid Chronic Toxicity	Waiver	-----	----	Footnote 6
850.1350	Mysid Chronic Toxicity	Waiver	-----	----	Footnote 6
850.1400	Fish early life-stage toxicity test	Waiver	-----	----	Footnote 6
850.1400	Fish early-life stage toxicity test	Waiver	-----	----	Footnote 6
850.1730	Accumulation – In Fish	Waiver	-----	----	Footnote 6
850.4100	Seedling Emergence and Seedling Growth	Waiver	-----	----	Footnote 6
850.4150	Vegetative Vigor	Waiver	-----	----	Footnote 6
850.4400	Aquatic Plant Toxicity Using Lemna	Waiver	-----	----	Footnote 6
850.4500	Algal Toxicity	Waiver	-----	----	Footnote 6
850.4550	Cyanobacteria	Waiver	-----	----	Footnote 6

ENVIRONMENTAL FATE

835.2130	Hydrolysis as a Function of pH and Temperature	Waiver	-----	----	Footnote 7
835.2240	Photodegradation in Water	Waiver	-----	----	Footnote 7
835.2410	Photodegradation in Soil	Waiver	-----	----	
835.1240	Soil Leaching & Absorption/Desorption	Waiver	-----	----	Footnote 7
835.4100	Aerobic Soil Metabolism	Waiver	-----	----	Footnote 7
835.4300	Aerobic Aquatic Metabolism	Waiver	-----	----	Footnote 7
835.4400	Anaerobic Aquatic Metabolism	Waiver	-----	----	Footnote 7
835.3110	Ready Biodegradability	Waiver	-----	----	Footnote 7
835.3220	Porous Pot Test	Waiver	-----	----	Footnote 7
835.3240	Simulation Test-Aerobic Sewage Treatment/Activated Sludge	Waiver	-----	----	Footnote 7
835.3280	Simulation Tests to Assess the Biodegradability of Chemicals	Waiver	-----	----	Footnote 7

Signature <i>Michael Harvey</i>	Name and Title: Michael Harvey, CEO	Date 7-5-2019
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Ingredient(s): Octanoic Acid – Generic Matrix for Technical Active					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.3300	Modified Activated Sludge, Respiration Inhibition Test		-----	-----	Footnote 7
OCCUPATIONAL AND RESIDENTIAL EXPOSURE					
875.1100/1200	Dermal Exposure –Indoor and Outdoor	Waiver	-----	-----	Footnote 8
875.1300/1400	Inhalation Exposure – Indoor and Outdoor	Waiver	-----	-----	Footnote 8
875.1600	Data Reporting and Calculations	Waiver	-----	-----	Footnote 8
875.1700	Product Use Information	CITE-ALL	-----	-----	
870.2400	Dermal Exposure – Post Application	Waiver	-----	-----	Footnote 8
870.2500	Inhalation Exposure – Post Application	Waiver	-----	-----	Footnote 8
870.2700	Product Use Information	CITE-ALL	-----	-----	
875.2800	Description of Human Activity	CITE-ALL	-----	-----	
RESIDUE CHEMISTRY					
860.1100	Chemical Identity	Insert P. Chem MRID			
860.1200	Directions for Use	----	-----	-----	Footnote 9
860.1460	Food-Handling	Waiver	-----	-----	Footnote 9
None	Nature of the Residues on Surfaces	Waiver	-----	-----	Footnote 10
860.1300	Nature of the Residue in Plants	Waiver			Footnote 10
860.1340	Residue Analytical Method	Waiver			Footnote 10
860.1400	Irrigated Crops	Waiver			Footnote 10
860.1480	Meat/Milk/Poultry/Eggs	Waiver			Footnote 10
860.1500	Crop Field Trials (food commodities)	Waiver			Footnote 10

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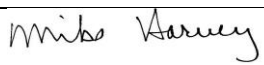
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				Note

Footnotes:

1. As indicated in the Human Health Scoping Document noted above, the Agency relied on a 14-day oral study to satisfy the 90-day oral data requirement (see page 41 of the document).
2. As indicated in the Human Health Scoping Document, the Agency relied on the published literature to satisfy the repeat dose dermal toxicity data requirement (see pages 41-42 of the document).
3. As indicated in the Human Health Scoping Document, the Agency relied on a dermal chronic toxicity/carcinogenicity study in mice with nonanoic acid to satisfy all chronic/oncogenicity data requirements for octanoic acid. No studies were required or cited for oral exposure since octanoic acid is a GRAS substance and naturally occurs in animal and vegetable fats. Refer to pages 39 and 42 of the Scoping Document.
4. These data requirements were not required for the Registration Review of octanoic acid and no studies were cited in the Agency's Human Health Scoping Document.
5. According to the Agency's Human Health Scoping Document, data is available on octanoic and nonanoic acid. The octanoic acid data is from the published literature while the nonanoic acid studies were previously submitted to the Agency and are cited in this data matrix.
6. According to the Agency's document "Summary of Product Chemistry, Environmental Fate, and Ecotoxicity for the Caprylic Acid Registration Review", all ecotoxicity studies have been waived for octanoic acid. Specifically, the document stated: "The Agency has waived all Ecological Effects data requirements for the active ingredient caprylic acid. Caprylic acid is naturally occurring in vegetable oils and animal fats. Fatty acids are a significant part of the normal daily diet of mammals, birds and invertebrates. It is a minimal risk and low concern inert and is readily metabolized by all forms of life" (see page 10 of the document).
7. According to the Agency's document "Summary of Product Chemistry, Environmental Fate, and Ecotoxicity for the Caprylic Acid Registration Review", all environmental fate studies have been waived for octanoic acid. The document noted that ... caprylic acid occurs in a number of plants, and animal sources such as animal oils, fats, butter, coconut oil, etc. ... Microorganisms rapidly degrade fatty acids in soil. The breakdown products of fatty acids are expected to be carbon dioxide and water. Therefore, the Agency is not requiring any environmental fate or ecological effects studies at this time" (see page 9 of the document).
8. According to the Agency's Human Health Scoping Document, "... a quantitative risk assessment is not required, because, again, adverse systemic effects on man attributable to the dermal and inhalation routes of exposure to caprylic acid are not expected" (see pages 44-45 of the document).

Signature		Name and Title: Michael Harvey, CEO	Date
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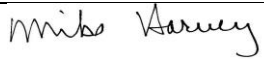
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status
				Note

9. The "Directions for Use" are on the product label for ReducX.
10. According to the Agency's Human Health Scoping Document, no residue chemistry studies are required since a dietary exposure assessment is not necessary. The basis for this position is the GRAS status of octanoic acid, its use as a direct food ingredient and the lack of any toxicology endpoints of concern (see pages 43-44 of the document).

Signature		Name and Title: Michael Harvey, CEO	Date
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